DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3701. Misbranding of amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. Robert M. Walker (Closson-Kelly Drugs), and James Mason. Plea of guilty by Robert M. Walker. Sentence of 6 months in jail on each of 3 counts, to run concurrently. Plea of not guilty by James Mason. Tried to a jury. Verdict of not guilty. (F. D. C. No. 31284. Sample Nos. 29849—L to 29852—L, incl., 29976—L to 29979—L, incl.)

INFORMATION FILED: November 28, 1951, Western District of Washington, against Robert M. Walker, trading as Closson-Kelly Drugs, at Seattle, Wash., and James Mason, an employee of Closson-Kelly Drugs.

INTERSTATE SHIPMENT: Prior to the sales described below, various quantities of amphetamine sulfate tablets were shipped into the State of Washington, from New York, N. Y., and various quantities of Seconal Sodium capsules were shipped into the State of Washington, from Indianapolis, Ind.

ALLEGED VIOLATION: On March 29 and 30 and April 2, 3, and 5, 1951, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear any directions for use.

Further misbranding, Section 502 (d), the Seconal Sodium capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged amphetamine sulfate tablets failed to bear a label containing the common or usual name of the drug.

Disposition: On March 26, 1952, James Mason having entered a plea of not guilty to each of the 6 counts in which he was charged, he was tried to a jury, which returned a verdict of not guilty.

On April 10, 1952, Robert M. Walker changed his plea from not guilty to guilty on each of 3 counts of the information, and he was sentenced to 6 months in prison on each of these counts, the sentences to run concurrently. The remaining counts of the information against Robert M. Walker were dismissed on motion of the Government.

3702. Misbranding of dextro-amphetamine sulfate tablets, pentobarbital sodium capsules, and Seconal Sodium capsules. U. S. v. Georgia Drug Store, Inc., and Willie W. Gross, Sr. Pleas of nolo contendere. Georgia Drug Store, Inc., fined \$250. Willie W. Gross, Sr., placed on probation for two years, conditioned that he serve three months in jail if corporation failed to pay fine. (F. D. C. No. 31297. Sample Nos. 777-L, 1313-L, 1315-L, 1316-L, 1511-L, 1512-L.)

INFORMATION FILED: February 12, 1952, against Georgia Drug Store, Inc., Atlanta, Ga., and Willie W. Gross, Sr., president of the corporation.

INTERSTATE SHIPMENT: Within the period from on or about September 22, 1950, to on or about April 5, 1951, various quantities of dextro-amphetamine sulfate tablets, pentobarbital sodium capsules, and Seconal Sodium capsules were shipped in interstate commerce from the States of Pennsylvania, Illinois, and Indiana, into the State of Georgia.

ALLEGED VIOLATION: On April 23, 26, 27, and 28, and May 1 and 2, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the pentobarbital sodium capsules and the Seconal Sodium capsules contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged dextroamphetamine sulfate tablets failed to bear a label containing the common or usual name of each active ingredient of the drug.

DISPOSITION: February 29, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of \$250 against the corporation and placed Willie W. Gross, Sr., on probation for 2 years, conditioned that if the fine levied on the corporation were not paid, he would serve 3 months in jail.

3703. Misbranding of amphetamine sulfate tablets and dextro-amphetamine sulfate tablets. U. S. v. Fred G. Hansard (H & Y Drug), and Arvil Cravens. Fred G. Hansard pleaded nolo contendere and fined \$100 on count 1, \$500 on count 2, and placed on probation for 2 years on remaining 3 counts. Arvil Cravens pleaded guilty and sentenced to 5 days in jail and \$100 fine on count 2 and placed on probation for 2 years. (F. D. C. No. 31269. Sample Nos. 13660-L to 13664-L, incl.)

INFORMATION FILED: December 5, 1951, Northern District of Texas, against Fred G. Hansard, trading as the H & Y Drug, at Amarillo, Tex., and Arvil Cravens, pharmacist.

INTERSTATE SHIPMENT: On or about November 13 and 14, 1950, and February 5, 1951, from Philadelphia, Pa., and Wichita, Kans., of quantities of amphetamine sulfate tablets and dextro-amphetamine sulfate tablets.

ALLEGED VIOLATION: On February 2, 3, 4, and 6, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the drugs being misbranded. Fred G. Hansard was charged with the violations involved in each of the 5 counts of the information, and Arvil Cravens was joined as a defendant in counts 2 and 5 and was charged with the violations involved in those counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the